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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/690,473

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Brett Haarala

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22852

7590

03/19/2003

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EXAMINER

HAYES, MICHAEL J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/690,473

Applicant(s)

HAARALA ET AL.7

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-90,92-101 and 103-159 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-90,92-101 and 103-159 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 60, 61, 63-68, 70-72, 74-79 are rejected under 35 U.S.C. 102(b) as being anticipated by HANCOCK et al. (U. S. Patent No. 4,840,615). Hancock discloses an access port having upper and lower bodies, an outlet for attaching a catheter, entry and access sites located throughout a common septum, whereas the entry and access sites include perpendicular sites to each other or to the outlet that extend in a direction away from the reservoir to help define the reservoir volume and the wall thickness of the device. Hancock discloses that the septum outer surface is exposed exteriorly in one embodiment (5:16-20). See also Figs. 1, 4, 5, 9, 19 and related text.

Claims 60-90, 92-101, 103-112, 132-139, 141-147, 149-155, 157-159 are rejected under 35 U.S.C. 102(b) as being anticipated by DALTON (U. S. Patent No. 4,857,053). Dalton discloses an access port made from titanium having upper and lower bodies, an outlet for attaching a catheter, suture holes, entry and access sites located in a common septum that are perpendicular to each other or to the outlet, extending in a direction away from the reservoir to

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define reservoir volume and septum wall thickness. The upper body or body portion 30 includes target areas or holes for entry and access sites. Upper body 30 comprises raised edges that surround a given target area. See Figs. 4-6; col. 5, line 66 - col. 6, line 48.

Claims 81-85, 88, and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by CONE et al. (U. S. Patent No. 5,108,377). Cone discloses an access port including titanium body portion of upper and lower body parts, reservoir, outlet, entry site defined by a hole in the portion. The septum is located horizontally between the septum and lower body part as seen in Fig. 3. The access and entry sites are located in the common septum 22.

Claims 103, 104, 105, 107, 108, 110-112, and 157 are rejected under 35 U.S.C. 102(e) as being anticipated by TUCKER. Tucker discloses an access port including a titanium body portion of upper and lower parts, reservoir, outlet with catheter, septum having access and entry sites defined by a target hole, a raised edge around the target area opening and suture holes. See Figs. 1,2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60-65, 68, 69, 81-85, 89-90, 92-96, 100, 101, 103-107, 111, 112, 141-143, 146, 147, 157, and 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over MITTLEMAN (U. S. Patent No. 4,000,740) in view of TUCKER (U. S. Patent No. 5,718,682). Mittleman

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discloses an access port including upper and lower 12 body portions, a guidewire/stylet entry site 16 sealed with a septum 26, an access site 42, and a raised edge surrounding the target area of the access site. Mittleman discloses the access site orientated perpendicular to guidewire site and the outlet because the site is placed perpendicular to an axis line drawn between the guidewire site and the outlet. Mittleman does not disclose making the device of titanium or suture holes. Tucker teaches the use of titanium and suture holes to provide a nonreactive metal for the delivery of medications and to hold the device in place on a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Tucker in the device of Mittleman in order to provide a device compatible with bioactive fluids and to prevent injury during use that would result from the device moving in relation to the patient.

Claims 62, 69, 73, 80, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over HANCOCK or CONE as applied to claims 60, 70, or 91 above, and further in view of TUCKER. Hancock discloses the claimed invention except for using titanium to make the device and suture holes. Cone discloses the claimed invention except for suture holes. Tucker discloses the use of titanium and suture holes to provide a nonreactive metal for the delivery of medications and to hold the device in place on a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Tucker in the invention of Hancock or Cone to provide a device compatible with bioactive fluids and to prevent injury during use that would result from the device moving in relation to the patient.

Claims 113-131, 140, 148, and 156 are rejected under 35 U.S.C. 103(a) as being unpatentable over HANCOCK, DALTON, CONE, MITTLEMAN and/or TUCKER and further

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in view of LUTHER (U. S. Patent No. 5,403,283). Hancock, Dalton, Cone, Mittleman and/or Tucker disclose the recited invention as discussed above with respect to claims 60, 70, 81, 97, 98, 104, 106, and 109 except for a stylet. Luther teaches the use of a stylet 22 for introducing a catheter into the septum of a port (2:44-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Luther in the inventions of Mittleman and Tucker, Hancock, Cone, or Tucker alone in order to provide a safe method of catheterizing a port.

Claims 113-131, 140, 148, and 156 are rejected under 35 U.S.C. 103(a) as being unpatentable over HANCOCK, DALTON, CONE, MITTLEMAN and/or TUCKER and further in view of ENSMINGER et al. (U. S. Patent No. 5,556,381). Hancock, Dalton, Cone, Mittleman and/or Tucker disclose the recited invention as discussed above with respect to claims 60, 70, 81, 97, 98, 104, 106, and 109 except for a stylet. Ensminger teaches the use of a stylet for accessing an implanted catheter of a port (8:39-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Ensminger in the inventions of Mittleman and Tucker, Hancock, Cone, or Tucker alone in order to provide a safe controllable method of percutaneous access.

Response to Arguments

Applicant argues that neither Hancock nor Dalton disclose a septum's outer surface forming an exterior surface. The examiner disagrees because Hancock explicitly states that septum 28 can be exposed to tissue, requiring the outer surface to form an exterior surface (5:9-20). Dalton discloses two embodiments, one with an outer covering 66 and one without the covering. In the embodiment without the covering, the septum's outer surface forms an exterior

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surface (col. 5, line 66 - col. 6, line 48). The mesh outer material defines area openings or holes for entry and access sites.

Applicant argues that Cone is not configured to permit insertion of either a guidewire or stylet because of the arrangement of the connector 38 and bore 40. The examiner disagrees because the arrangement of the connector and bore establishes an open area through which a guidewire is capable of passing through (Figs. 3, 7, 8-11; 7:7-21).

Applicant argues that Tucker does not disclose an entry site disposed opposite to the outlet. The examiner disagrees because Tucker discloses an entry and access site positioned opposite from the outlet. The entry site is opposite because it is placed directly across from the outlet. The common meaning of "opposite" is "placed directly across from" (Webster's II New Riverside University Dictionary, 1994) and Applicant has not given the term his own special definition in the specification to distinguish from the common meaning.

Applicant argues that there is no motivation to combine the references of Mittleman and Tucker because Mittleman does not disclose implantable, biocompatible material and there would be no reason to modify Mittleman. The examiner first points out that Mittleman does teach the use of a biocompatible material. The device of Mittleman is for medicaments and parental fluids that are administered intravenously to a patient. Because the device contacts fluids that are delivered intravenously it will be made of a material that is biocompatible. As a medical device containing intravenous fluids the device would not be used unless it was made from biocompatible material. No medical personnel would use a non-biocompatible material that could leach monomers or other chemical substances into intravenous fluids which would endanger the health of the patient. Being biocompatible, the device is also capable of being

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implanted. Tucker is relied upon for the teaching of using Titanium (a known biocompatible material) as material of choice motivated by the reasons given above in the rejection under 35 USC 103.

Applicant expresses that it is not clear how Hancock, Dalton, Cone, Mittleman, and/or Tucker have been applied to independent claims 118 and 125. Applicant is referred to the paragraph rejection to 118 and 125 which, in turn, refers Applicant to the paragraphs explaining the teachings of Hancock, Dalton, Cone, Mittleman, and/or Tucker with respect to claims 60-112 in Office Action Paper No. 16. The position the examiner takes with respect to the references is set out clearly in the office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be

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reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh
18 March 2003



MICHAEL J. HAYES
PRIMARY EXAMINER